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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,813	04/20/2001	Robert Henry	54195-5001	3042

7590

02/13/2004

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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/839,813	Applicant(s) HENRY ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) 32-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE Acknowledgment

1. The request filed on November 12, 2003 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/838,813 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 22-30, and 32-42 are pending.

Claim 31 has been canceled.

Claims 32-42 have been withdrawn from consideration because the claims are drawn to non-elected inventions.

2. Claims 22-30 are examined in the present office action.

Oath/Declaration

3. The Oath/Declaration is objected to because the filing date for PCT/US00/24244 is 05 September, 2000 instead of 18 October, 1999 as is presently recited in the Oath/Declaration.

Priority

4. For Applicants to receive Foreign Priority from PCT/US00/24244, Applicants are required to submit a certified copy of said application.

Specification

5. The Brief Description of the Drawings is objected to because Figure 2 is referred to as "Fig. 2" instead of --Fig. 2A-2D--. Correction is required.

New Matter

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to high molecular weight DNA being obtainable by cesium chloride fractionation.

The before mentioned claimed invention does not have support in the presently filed application and is considered new matter.

103 Obviousness

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 22-25, 27, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turbin et al (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203).

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, wherein said isolated DNA is genomic DNA or wherein said DNA is high molecular weight DNA obtainable by cesium chloride fractionation or wherein a selection marker gene is present in a selection construct or wherein both donor and recipient are cereal plants. The claims are also drawn to transforming a species of *Oryza sativa*.

Turbin et al teach a method of transforming a barley plant with directly isolated genomic DNA isolated from another species of barley (page 61 and 62, see "Extraction of DNA from the endospermal material" and "Extraction of DNA from leaves"), which is a cereal plant. It would have been an inherent process of the Turbin et al method to propagate transformed plants (page 63, see "Examination of the pollen of plants grown from the injected grains"). The office interprets said DNA to be high molecular weight DNA because both processes of isolating DNA produce long molecules of DNA which would be obtainable by cesium chloride fractionation.

Turbin et al do not teach transforming a plant using microprojectile bombardment wherein the plant is a species of *Oryza sativa* and incorporating a selection marker gene in a construct.

Christou teaches a method of transforming *Oryza sativa*, cultivars Gulfmont, IR72 and Koshihikari using microprojectile bombardment and transforming a plant with a selection marker

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(the bar gene) gene that is present in a selection construct (page 201, sentence bridging left and right columns).

Given the recognition of those of ordinary skill in the art of the value of transforming rice for the purpose of moving rice improvement programs forward as taught by Christou (page 197, right column, 3rd and 4th sentence from the bottom), it would have been within the scope of one of ordinary skill in the art to modify the method of Turbin et al and to use the microprojectile bombardment method as taught by Christou. One of ordinary skill in the art would have used the directly isolated DNA method as taught by Turbin et al and to combine it with the method of DNA transfer as taught by Christou. The motivation is taught by Christou who states that microprojectile bombardment is “the best method for achieving truly genotype-independent transformation” (page 198, right column, 1st paragraph).

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicants contend that the Turbin et al document provides data that is considered dubious and unreproducible and has largely been ignored by persons of ordinary skill in the relevant art. Applicants have submitted a 37 C.F.R. §1.132 Declaration of Leonard Slade Lee which Applicants assert sets forth detailed facts and reasoning as to why Turbin et al would not be considered to teach “a method of transforming a barley plant” as set forth by the Examiner (page 9, 2nd full paragraph).

Lee contends that the data of Turbin et al is dubious and unreproducible and has been largely ignored by persons of ordinary skill in plant genetic engineering and based on Lee’s

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presented evidence, there is no motivation to combine Turbin et al with Christou (1997). Lee contends that Turbin et al is cited only ten times (page 2, paragraph 5). Lee contends that Kleinhofs & Behki (1977) assert that only one plant exhibited wild-type pollen grains in a high frequency and they state that “No controls with similarly prepared DNA from wx plants were reported” (page 2, paragraph 6). Lee contends that Kleinhofs & Behki cast doubt upon a subsequent analysis of a positive plant from the Turbin et al study (page 3, paragraph 7). Lee contends that the unexpected outcome as noted by Kleinhofs & Behki is published in a review article of Kado & Kleinhofs (1980) (page 3, paragraph 8). Lee contends that the barley plants of Turbin et al have not been transformed and the mechanism is not understood (page 3-4, paragraphs 9-11). Lee contends that Sanford et al (1984) use an analogous method to Turbin et al., and produce zero transformants out of 22,300 potential transformation events (page 4, paragraph 13). Lee contends that Holl and Olson (1983) assert that the results of Turbin et al have to be challenged because they believe contamination contributed to Turbin et al results and that there is considerable resistance to accept that direct addition of DNA can produce demonstrable and heritable effects (page 4, paragraph 14). Lee contends that the Turbin et al paper was cited in a review but was not addressed. It is Lee’s opinion that this means that no significant results are contributed by Turbin et al (page 4, paragraph 15). Lee contends that even though the Turbin et al research was published nearly 30 years ago, the method has not been utilized and it is the opinion of Lee that the Turbin et al method is similar to pollen tube transformation and that Huixia Shou et al (2002) state that pollen-tube pathway transformation is not reproducible (paragraph 16, bridging pages 4 and 5).

The Office asserts that the Declaration of Lee is based in part, on Lee's opinions and the opinions of other researchers and is not based on any published data in which the Turbin et al research was repeated. The fact that the Turbin et al reference is not widely cited, does not mean that the reference is not valid. Lee purports that there is one instance in which the Turbin et al research is repeated. The research of Sanford et al, which Lee claims is analogous, is actually not a repetition of the Turbin et al research. Turbin et al extracted DNA from endosperm cells of developing barley seeds and then microinjected the DNA into developing barley seeds. Sanford et al irradiated tomato pollen and then used the irradiated pollen to pollinate tomato plants (page 554, Material and methods section). Lastly, the mechanism by which the Turbin et al method works is irrelevant to the validity of the data.

The Office contends that the Turbin et al reference was used as a primary reference in the 103 rejection mainly for its contemplation and implementation of using isolated genomic DNA from a cereal crop to transform another cereal crop of the same species. Christou teaches particle bombardment and supplies the motivation to use this method as a superior method to transform plants. The Turbin et al reference was not chosen because of the actual transformation method, but rather, for the teachings of using isolated genomic DNA in a transformation method.

Applicants contend that one of skill in the art would not be motivated to combine the Turbin et al reference with the Christou reference because of the doubt cast upon the teachings of Turbin et al by numerous peer-reviewed articles and because of the irreproducibility of the Turbin et al reference (page 10 of the amendment, 1st full paragraph).

The Office contends that the "doubt cast upon the teachings of Turbin et al by numerous peer-reviewed articles" are merely the opinions of other researchers without any substantiated

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data. The “irreproducibility of the Turbin et al reference” is not correct as the Turbin et al method was not repeated. Lee interprets the methods of Sanford et al to be analogous to the methods of Turbin et al and this issue has been discussed above.

The Office contends that Applicants have disclosed unexpected results for claims drawn to a method of transferring a gene into an *Oryza sativa* plant comprising transforming an *Oryza sativa* plant using microprojectile bombardment of DNA isolated from *Zizania palustris*. But none of the claims have all the specified limitations and the scope of the claims does not reflect the disclosed facts. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

8. Claims 26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turbin et al (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203) as applied to claims 22-25, 27, 28, and 30 above, and further in view of Applicants' own admitted statement of the prior art (page 18, lines 17-18, Xiao et al 1996. Nature 384:223-) and Weining et al (1991 Theor. Appl. Genet. 82:209-216).

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, or wherein the DNA is high molecular weight DNA and a selection marker gene is present in a selection construct and wherein said donor plant and said recipient plant are members of different species or different genera or wherein both donor and recipient

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are cereal plants and the donor plant is a species of *Zizania palustris*. The claims are also drawn to transforming a species of *Oryza sativa*.

Turbin et al in view of Christou have been discussed above.

Turbin et al in view of Christou do not teach a donor plant and recipient plant from different genera nor where the donor plant is of the species *Zizania palustris*.

Applicants' admitted statement of the prior art teaches wild members of *Oryzae* have been shown to be important sources of genes for improvement of yield wherein *Zizania palustris* is a wild rice species but is classified as a different genus compared to *Oryzae*.

Weining et al teach isolation of DNA from grasses and cereal plants.

Given the recognition of those of ordinary skill in the art of the value of producing a rice plant transformed with high molecular DNA isolated from another species of rice plant and transformed by microprojectile bombardment as taught by Turbin et al in view of Christou (see above), it would have been obvious to use the method of Turbin et al in view of Christou and to modify this method taught by Applicants' own admitted statement of the prior art by isolating DNA from the wild rice species, *Zizania palustris* using the method as taught by Weining et al.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicants contend that the rejection is based upon the view that Turbin et al teach a method of transforming a barley plant with directly isolated and uncharacterized DNA.

Applicants assert that the grounds for rejection based on Turbin et al are improper and therefore the Examiner has not established a *prima facie* case of obviousness.

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The Office contends that the rejection is proper and arguments substantiating the Turbin et al reference are set forth above.

9. A single claim drawn to include the limitations of claims 29 and 30 would be free of the prior art.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read "Stuart F. Baum". The signature is fluid and cursive, with a long horizontal stroke at the end.

Stuart F. Baum Ph.D.

Patent Examiner

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January 30, 2004